Latest Revisions of the Common Rule and Implications for Research in Uganda and the Region

Jaime O. Hernandez, J.D., M.Be.
Pronouns: he/him/his
Public Health Program Analyst
Office for Human Research Protection (OHRP)
Department of Health and Human Services (HHS)

OASH | Office for Human Research Protections

1

OASH | Office for Human Research Protections

Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of OHRP or the U.S. Department of Health and Human Services

2

2

OASH Office for Human Research Protections

Learning Objectives

- Introduce the US Department of Health and Human Services regulations for the protection of research participants and the Comm Rule
- Discuss when the requirements of the Common Rule apply
- Introduce the 2018 revisions to the Common Rule and discuss its implications for research in Uganda and the region

3

3

HHS Regulations for the Protection of Research Participants

OASH Office for Human Research Protections

4

OASH Office for Human Research Protections

HHS Regulations on Human Research Protections: 45 CFR Part 46

Adopted by 19 US Federal department or agencies.

- Research funded by these departments or agencies must comply with the requirements of Subpart A

HHS Regulations:

Subpart A – The Common Rule

Subpart B – Pregnant women & fetuses

Subpart C – Prisoners

Subpart D – Children

Subpart E – IRB Registration

- Research funded by HHS, including the National Institute of Health (NIH), must comply with the requirements of **ALL** subparts

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

5

OHRP Office for Human Research Protections

5

When Do the Requirements of the Common Rule Apply?

OASH Office for Human Research Protections

6

OASH Office for Human Research Protections

Determining When the Requirements of the Common Rule Apply

- The HHS regulations apply to institutions that are **engaged in non-exempt, human subjects research** that is conducted or supported by HHS

§46.101

OASH Office for Human Research Protections

What if the Research is not Federally Funded?

- FDA regulations apply to some non-federally funded research
- Other Federal, state, local regulations may apply
- **Institutional policies**
  - Many institutions elect to apply the Common Rule or similar standards to all research, regardless of funding source

OASH Office for Human Research Protections

What if the Research Takes Place Outside of the United States?

- Regulations may also apply to research outside the United States (46.101(a)).
- When research covered by this policy **takes place in foreign countries**, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, **if a department or agency head** determines that the procedures prescribed by the institution afford **protections that are at least equivalent** to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy (46.101(h)).
- This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research (46.101(g)).

WHAT DOES THIS MEAN?

- **IF** the regulations apply, then they apply regardless of where the research takes place.
- When do the regulations apply?
  The HHS regulations apply to **institutions that are engaged in non-exempt, human subjects research** that is conducted or supported by HHS

9

9

OASH Office for Human Research Protections

Determining When the Requirements of the Common Rule Apply

- The HHS regulations apply to institutions that are **engaged in non-exempt, human subjects research** that is conducted or supported by HHS
- To determine if your project is non-exempt human subjects research, ask these questions in this order:

1. Does the activity involve ***Research*** (46.102(l))?
2. Does the research involve ***Human Subjects*** (46.102(e))?
3. Is the human subjects research ***Exempt*** (46.104)?
4. Is my institution ***Engaged*** in the non-exempt, human subjects research? (See, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)

Ask these questions about the full research protocol

Ask this questions about your institution only

10

10

OASH Office for Human Research Protections

Some Potential Scenarios

- Uganda institution only:
  - Uganda institution is the direct and sole recipient of HHS funding to conduct non-exempt, human subjects research
- US institution only in Uganda:
  - US institution is the direct and sole recipient of HHS funding to conduct non-exempt, human subjects research in Uganda, but there is no collaboration with any Uganda institution
- US and Uganda institutions collaborating:
  - Both a US and a Uganda institution are engaged in the same non-exempt, human subjects research study sponsored by HHS

11

11

2018 Revisions to the Common Rule

OASH Office for Human Research Protections

12

13

OASH Office for Human Research Protections

Helpful Terminology

- Pre-2018 Rule or pre-2018 Requirements:
  - The Common Rule as published in the 2016 edition of the Code of Federal Regulations (i.e., 45 CFR 46 subpart A, originally promulgated in 1991 and subsequently amended in 2005).
- 2018 Rule, 2018 Requirements, or revised Common Rule:
  - The Common Rule published in the Federal Register on January 19, 2017 (82 FR 7149), further amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).

13

13

14

OASH Office for Human Research Protections

Rationale for Updating the Common Rule

- Promoting individual autonomy
  - Improving the informed consent process
  - Adding broad consent option for secondary research
- Reducing administrative burden to IRB processes to allow for more attention to research that is more than minimal risk
  - Removing activities from the definition of research
  - Expanding exempt research
  - Using single IRB review (January 20, 2020)

14

14

15

OASH Office for Human Research Protections

Some Changes in the 2018 Requirements:

Changes to the Common Rule	Potential Effect for Research in Uganda and the Region
• Certain activities were excluded from the definition of research ○ Including certain public health surveillance activities (see, 46.102(L)(2))	Activities that are not "research" or are exempt from the regulations are not required to comply with the requirements of the regulations: • Uganda institution only • US institution only in Uganda • US and Uganda institutions collaborating • IRB approval is not required • Informed consent is not required • Other requirements may apply, such as your local regulations, HIPAA, or requirements for conducting public health surveillance activities (but these are not under the Common Rule)
• Exemptions to the Common Rule (46.104(d)) were generally expanded, so that more research may qualify for exemptions • Two new exemptions were added for secondary research with information of biospecimens (see, 46.104(d)(7)-(8))	
• Single IRB requirement: US institutions engaged in cooperative research must rely on approval by a single IRB for the portion of the research that is conducted in the US (46.114(b)(1)).	• Uganda institution only • US institution only in Uganda • US and Uganda institutions collaborating • NOT APPLICABLE

15

15

16

OASH Office for Human Research Protections

Some Changes to Informed Consent in the 2018 Requirements

- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research (46.116(a)(5)(i)).
- Some new Basic Elements (46.116(b)) and some new Additional Elements (46.116(c)) of informed consent
- Some new drafting standards for the type of information included (116(a)(4)) and how it should be organized and presented (116(a)(5)(ii))
  - Purpose is to facilitates the subject's understanding of the reasons **why one might or might not want to participate**

16

16

OASH Office for Human Research Protections

Some Changes to Informed Consent in the 2018 Requirements

- Addition of Broad Consent for the future storage and research use of identifiable information or identifiable biospecimens:
  - Broad consent is optional
  - Available only for secondary research
    - Information or biospecimens originally collected for non-research purposes or for a different research study
  - Allows for less specificity in the consent document than traditional informed consent, but it must comply with standards at 46.116(d)

17

17

OASH Office for Human Research Protections

Some Changes to Informed Consent in the 2018 Requirements

- Potential Effect for Research in Uganda and the Region:
  - Uganda institution only → Informed consent must comply with these new standards (unless waived)
  - US institution only in Uganda → US institution's informed consent must comply with these standards (unless waived), so Uganda's authorities may encounter these new standards
  - US and Uganda institutions collaborating → All informed consent forms must comply with these standards (there may be different forms for different locations)

18

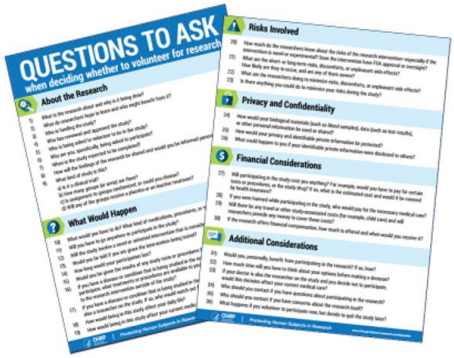
18

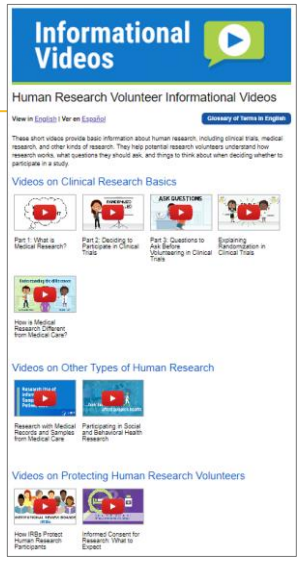
OASH Office for Human Research Protections

Resources for Research Participants

Videos, Infographics, & More in English and Spanish

https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html





19

19

OASH Office for Human Research Protections

Resources for Research Teams

- Human Research Protection Training: https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html
- Resources on the revised Common Rule: www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html
- Other videos (*e.g.*, simplifying informed consent): https://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/index.html

20

20

OASH Office for Human Research Protections

Contacts Us

- Contact us OHRP@hhs.gov
- Visit OHRP website at www.hhs.gov/ohrp

21